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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,338	04/01/2004	John K. Morris	7107-4CIP	7535
30448	7590	11/02/2006		EXAMINER
AKERMAN SENTERFITT				ANDERSEN, MICHAEL T
P.O. BOX 3188				
WEST PALM BEACH, FL 33402-3188			ART UNIT	PAPER NUMBER
			3734	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/815,338	MORRIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	M. Thomas Andersen	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/05, 4/18/05</u>   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statements (IDS) received on 10/24/2005 and 4/18/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Specification***

The disclosure is objected to because of the following minor informalities: page 3, line 11 “of” should be inserted between “capable undergoing” ; page 16, line 14 “serrations 8” may be mislabeled ; page 18, line 23 “with the” should be deleted.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 10-12, 14, 20-21, 26-29, and 33-37 rejected under 35 U.S.C. 102(b) as being anticipated by Uwaydah, EP 0792621. Uwaydah discloses a malleable needle 18 constructed to deliver suture, a handheld instrument 2, a force-supplying structure 48, a proximal insertion opening (12a or 14b), and the needle has some degree of spring back (from 0 to about 100 percent). Uwaydah further discloses a jaw pivotally coupled to the distal end of the handheld instrument for holding tissue as the needle portion and suture material enters the tissue. The jaw includes an aperture to receive the deformed needle portion. Depending on what is

defined as the “portion of the needle” it will be curved or straight upon exiting the distal end of the handheld instrument. If the distal-most end of the needle is chosen as the “portion,” it will be straight upon exiting the handheld instrument; otherwise, the portion will be curved.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uwaydah in view of Green, U.S. 4,616,650. Uwaydah fails to disclose a narrowing slot. Green teaches in figure 1 and column 6, lines 38-40 that a wider entrance area of a slot facilitates an object entry therein. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the slot wider at the entrance making it easier for the needle to enter the slot.

Claims 5-9, 15-19, 30-32 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uwaydah as applied to claims 1, 4, 10, 14, 26, 29, 33 and 37 above, and further in view of Bendel, U.S. 5,219,358. Uwaydah fails to disclose a nitinol needle and a specific spring back percentage. However, Bendel discloses a nitinol needle that curves as it exits a suturing instrument. Bendel discloses, “we refer to the curved needle as being in the shape of an arc, although clearly the needle could have any “remembered” shape desired.” Bendel, col. 2, lines 50-53. In essence, Bendel is disclosing that any combination of Nickel or Titanium is well known in the art. Therefore, it would have been obvious to one having ordinary

skill in the art at the time of the invention to combine different percentages of Nickel and Titanium, and this would result in a wide range of "spring back," including 0 to 10 percent or 90 to 100 percent. Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to either forcibly straighten or forcibly curve the needle upon insertion into the handheld instrument. Such a factor depends on the alloy of nitinol, which, as explained above, is well known in the art to vary.

Claims 22-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uwaydah as applied to claim 21 above, and further in view of Schulsinger, U.S. 5,897,572. Uwaydah fails to disclose flat sides or a needle length of about 15mm or less. However, Schulsinger discloses that it is well known in the art to make needles having lengths of 15 mm or less (column 1, line 64). It would have been obvious to one of ordinary skill in the art at the time of the invention to make Uwaydah's needle to have a length less than 15 mm, as taught by Schulsinger to manipulate the needle in "microsurgical techniques." Further, Schulsinger discloses flat sides of the needle in figure 4. Using a needle with flat sides allows for better stability and better control than convention needles (col. 2, lines 15-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a needle with flat sides in view of Schulsinger.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uwaydah as applied to claim 21 above, and further in view of Gordon, U.S. 5,578,044. Uwaydah fails to disclose an indented portion. However, Gordon teaches indented portions 190 (figure 2) and 252 (figure 2D) enabling the needle to be held by a receiving member. It would have been obvious

to one of ordinary skill in the art at the time of the invention to make indentations on the needle enabling it to be more effectively secured by a receiving member.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10, 21, 26 and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, 19 and 25 of U.S. Patent No. 7,112,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each recite a malleable needle portion, a handheld instrument, and a force-supplying structure. The application's claim 1 corresponds to the patent's claim 1; claim 10 to claim 11 (because of the jaw limitation); claim 21 to claim 25; claim 26 to claim 1; claim 33 to claim 1 (because the method is merely providing the structure of the suturing instrument).

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

October 27, 2006



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER